

Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-07-26
Investment Auto Submission Date: 2012-02-24
Date of Last Investment Detail Update: 2012-06-28
Date of Last Exhibit 300A Update: 2012-07-26
Date of Last Revision: 2012-07-26

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA OC User Fee and Financial Reporting Systems

2. Unique Investment Identifier (Ull): 009-000005323

Section B: Investment Detail

- Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

The UFFRS investment supports the Division of User Fees (DUF) within FDA's Office of Financial Management (OFM). DUF is responsible for managing User Fees in compliance with the OMB Circular A-25 other relevant Legislative or Executive actions. Investment business functions include Fee collection, accounting, and reporting of the approximately \$3,000,000,000 collected annually in user fees. It also includes automated support for FDA strategic planning, budgeting, and budget execution that depends on the successful collection and distribution of mandated user fees. UFFMS functions directly enable compliance with the following legislation: Animal Drug User Fee Act (ADUFA); Animal Generic Drug User Fee Act (AGDUFA); Color Certification (CERTS); Exports Certificate (Exports); Medical Device User Fee Act (MDUFMA); Mammography Quality Standards Act (MQSA); Prescription Drug User Fee Act (PDUFA); Family Smoking Prevention and Tobacco Control Act (Tobacco). Contracts that support UFFRS operate, maintain and enhance three systems that collectively support the spending plans for the User Fee program and associated 5 year plans, and prepare the cost reporting needed to ensure statutory triggers are met. Contracts that support UFFRS operate, maintain and enhance three systems that collectively support the spending plans for the User Fee program and associated 5 year plans, and prepare the cost reporting needed to ensure statutory triggers are met. 1) The User Fee System (UFS) processes accounts receivable for user fee invoicing, collections, reconciliation with UFMS and detail

reporting. 2) FDA's Hyperion reporting system captures data at a summarized level, rather than at an individual transaction level. It is used to project the impact of User Fees FDA budgets, obligations, and expenditures. 3) The Business Intelligence Reporting System (BIRS) supports managerial reporting needs including web access to user fee information. BIRS uses Oracle Business Intelligence Enterprise Edition Plus (OBIEE) to provide business visibility and insight into the collection and use of User Fee revenues. UFFRS systems interface with HHS' Unified Financial Management System (UFMS) for both payment related processes, budget management and report generation, and changes to UFMS operations or features must be reflected in the UFFRS systems.

2. How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.

FDA's regulatory mission could not be met without the fees mandated by User Fee legislation and collected, managed and reported through UFFRS. The fees processed are a significant portion of FDA's budget. Many FDA missions would suffer if user fees are tracked from collection to work performed. Three quarters of the annual investment budget is for O&M activities that support user fee management. They include: - licenses support from the COTS vendors and technical upgrades to the COTS product to maintain our vendor support agreements; - software upgrades to remain compliant with increasing security requirements and FDA's Production environment; - help desk support; operation of the critical interfaces with UFMS including nightly extract, transfer, and load activities (ETL); - ongoing training, and changes needed to retain compatibility with UFMS. The cost for such support is reflected in the recently awarded contracts for fixed price operational support for the next five years. Although UFFRS meets current requirements, the user fee environment has been and continues to be dynamic. Changes expected in the next three years include: full implementation of the Food Safety Modernization Act; actions on Generic Drugs that will affect User Fees collections; demands for integrating additional data sources to improve the capabilities of BIRS; and a planned Oracle database upgrade. Changes to the FDA budget may require realignment that will trigger additional forecasting and reporting needs since User Fees are a significant source of FDA revenues; UFS, BIRS and Hyperion will require modification. Estimates for these costs are included in the new contracts. The ability to collect and adequately track and report approximately one billion dollars in revenue generated by user fees is critical to FDA and to HHS. Failure to maintain the automated capability to ensure adequate collection and accountability would have a serious negative impact on FDA. Comprehensive requirements for reporting are included in the legislation which FDA must meet to satisfy Congress and industry, as well as the general public. In addition, significant cuts could require partial or total termination of current contracts. The User Fee program is a valued source of revenue for FDA and many of its programs. Cuts to the UFFMS investment which would make it less able to collect and manage User Fees would be counter-productive at best.

3. Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.

In addition to transitioning to new vendors on FFP contracts, accomplishments include: 1) BIRS. Improved automation through scripts to increase the efficiency of automated

stakeholder notification of ETL success; substantially improved query response time on multiple reports (e.g. decreased time from > 5 minutes to

4. Provide a list of planned accomplishments for current year (CY) and budget year (BY).

As noted in response to Question 2, all UFFRS systems are in the Operations and Maintenance phase of their lifecycle. Three-quarters of the annual UFFRS budget is for O&M activities. The primary objective for FY12 and FY13 is to maintain at least the current standards of performance for existing services and, where possible, to improve them as was done in FY11. Operational services required by the new User Fee System contract include: 1) operations, support, and maintenance and 2) operational and financial reporting, and financial management. Services contractually required for BIRS include support and maintenance including data extracts, transfers, and loads (ETL) from HHS' UFMS, system monitoring and trouble-shooting, customer service and security support. Services required for Hyperion also include data loads, customer and security support, and maintenance services. Planned operational improvements include: Incorporating the application(s) into an automated ticketing system, Automating configuration management, and Improving the process for migration of data from development to test to production. Planned and probable enhancements include those needed to adapt to changes in business and/or the FDA technical environment. Significant challenges include responding to food safety legislation, actions on generic drugs that will affect User Fees collection, demands for integration of additional data sources to improve the capabilities of BIRS, and the planned Oracle upgrade. Congressional actions may also require budget realignments that could trigger additional forecasting and reporting needs since User Fee dollars are a source of FDA revenues. Two of these enhancements were started in FY11 and will continue into FY12: 1) FSMA legislation passed in 2011 authorized FDA to begin collecting fees for issuance of export certificates for animal feed and food product. To comply with FSMA, the User Fee systems need to be enhanced to collect fees for food and animal feed export certificates and to report related financial impacts. 2) Because FDA OIM is upgrading its database to Oracle 11g the User Fee system and its associated Rapid DataMart must also be upgraded. Similar enhancements are anticipated for FY12 and FY13.

5. Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.

2010-08-17

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

| | PY-1 & Prior | PY 2011 | CY 2012 | BY 2013 |
|--|--------------------|------------|------------|------------|
| Planning Costs: | \$0.4 | \$0.8 | \$0.8 | \$0.8 |
| DME (Excluding Planning) Costs: | \$72.4 | \$1.5 | \$1.4 | \$1.4 |
| DME (Including Planning) Govt. FTEs: | \$0.3 | \$0.1 | \$0.1 | \$0.1 |
| Sub-Total DME (Including Govt. FTE): | \$73.1 | \$2.4 | \$2.3 | \$2.3 |
| O & M Costs: | \$33.7 | \$7.7 | \$6.1 | \$6.2 |
| O & M Govt. FTEs: | \$1.5 | \$0.3 | \$0.3 | \$0.3 |
| Sub-Total O & M Costs (Including Govt. FTE): | \$35.2 | \$8.0 | \$6.4 | \$6.5 |
| Total Cost (Including Govt. FTE): | \$108.3 | \$10.4 | \$8.7 | \$8.8 |
| Total Govt. FTE costs: | \$1.8 | \$0.4 | \$0.4 | \$0.4 |
| # of FTE rep by costs: | 15 | 3 | 3 | 3 |
| | | | | |
| Total change from prior year final President's Budget (\$) | | \$1.3 | \$-0.2 | |
| Total change from prior year final President's Budget (%) | | 13.74% | -2.45% | |

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

Changes resulted from: 3 new acquisitions, replacing 4 existing ones; the archiving of 2 systems (CAS and AMS); expanded reporting needs including the integration of OBIEE; and the increasing emphasis on operations and services with decreasing new development.

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

| Contract Type | EVM Required | Contracting Agency ID | Procurement Instrument Identifier (PIID) | Indefinite Delivery Vehicle (IDV) Reference ID | IDV Agency ID | Solicitation ID | Ultimate Contract Value (\$M) | Type | PBSA ? | Effective Date | Actual or Expected End Date |
|---------------|--------------|-----------------------------------|--|--|---------------|-----------------|---------------------------------------|------|----------------|------------------|---|
| Awarded | | HHSF223201010740G | | | | | | | | | |
| Awarded | | HHSF223201110005i | | | | | | | | | |
| | | | | | | Solicitation ID | Type of Contract/Task Order (Pricing) | PBSA | Effective date | Extent Completed | Short description of acquisition |
| | | | | | | | Firm Fixed Price | Y | 2012-05-10 | U | HYPERION AND OBIEE SUPPORT AND MAINTENANCE SERVICES |
| Awarded | | HHSF223201110013C | | | | | | | | | |

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:
 Contracts and task orders appropriately require earned value.

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-07-26

Section B: Project Execution Data

Table II.B.1 Projects

| Project ID | Project Name | Project Description | Project Start Date | Project Completion Date | Project Lifecycle Cost (\$M) |
|------------|-------------------------------------|--|--------------------|-------------------------|------------------------------|
| 283663 | FDA OC User Fee System Enhancements | <p>The User Fee System (UFS) processes accounts receivable for user fee invoicing, collections, and detail reporting. UFS is a mission critical system that is in production. Approximately 75% of its annual budget is for operations and maintenance. The remainder is budgeted for enhancements.</p> <p>Enhancements response to include Legislative actions related to User Fees, changes in the user fee regulations which require corresponding adjustments in the system, major technical upgrades to maintain licenses or respond to CHDC requirements, changes required to adapt to modifications in UFMS that affect USF data imports or exports, or changes as a result of user request or additional functional requirements from within the FDA user community. The UFS support contract has an IDIQ component with a ceiling of 1500 per year that can be used for these</p> | | | |

Table II.B.1 Projects

| Project ID | Project Name | Project Description | Project Start Date | Project Completion Date | Project Lifecycle Cost (\$M) |
|------------|---------------------------------|--|--------------------|-------------------------|------------------------------|
| 283941 | FDA OC Hyperion Planning System | <p>enhancements using an abbreviated version of the EPLC.</p> <p>FDA's Hyperion Planning system captures User Fee data at a summarized level, rather than at an individual transaction level. It is used to project the impact of User Fees on FDA budgets, obligations, and expenditures including: 1) Annual budgets for each component of the FDA; 2) Allowance amounts issued to date; and iii) Transfers of funds between all FDA components. Hyperion is a mission critical system that is in production. Approximately 75% of its annual budget is for operations and maintenance. The remainder is budgeted for enhancements. Enhancements include response to Legislative actions related to User Fees, changes in the user fee regulations which require corresponding adjustments in the system, major technical upgrades to maintain licenses or respond to CHDC requirements, changes required to adapt to modifications in UFMS that affect Hyperion data imports or exports, or changes as a result of user request such as new reporting requirements to respond to internal business or administrative requirements from within the FDA user community. The Hyperion support contract has an IDIQ component with a ceiling of .340 Million per year that can be used for these enhancements using an abbreviated version of the EPLC.</p> | | | |

Table II.B.1 Projects

| Project ID | Project Name | Project Description | Project Start Date | Project Completion Date | Project Lifecycle Cost (\$M) |
|------------|---|--|--------------------|-------------------------|------------------------------|
| 284598 | FDA OC Business Intelligence Reporting System | <p>The Business Intelligence Reporting System (BIRS) is a mission critical system that is in production. Approximately 75% of its annual budget is for operations and maintenance. The remainder is budgeted for enhancements. Enhancements include response to Legislative actions related to User Fees, changes in the user fee regulations which require corresponding adjustments in the system, major technical upgrades to maintain licenses or respond to CHDC requirements, changes required to adapt to modifications in UFMS that affect Hyperion data imports or exports, or changes as a result of user request such as new reporting requirements to respond to internal business or administrative requirements from within the FDA user community.</p> <p>BIRS support contract has an IDIQ component with a ceiling of .340 Million per year that can be used for these enhancements using an abbreviated version of the EPLC. The first IDIQ task planned to be awarded with FY11 monies is to improve the current OBIEE data warehouse by adding Payable Analytics, and to make some planning capabilities currently in Hyperion available in the OBIEE environment that supports BIRS. This enhancement will include an OBIEE presentation layer for Hyperion and 10 to 12 dashboard reports.</p> | | | |

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

| Project ID | Name | Total Cost of Project Activities (\$M) | End Point Schedule Variance (in days) | End Point Schedule Variance (%) | Cost Variance (\$M) | Cost Variance (%) | Total Planned Cost (\$M) | Count of Activities |
|------------|---|--|---------------------------------------|---------------------------------|----------------------|-------------------|--------------------------|---------------------|
| 283663 | FDA OC User Fee System Enhancements | | | | | | | |
| 283941 | FDA OC Hyperion Planning System | | | | | | | |
| 284598 | FDA OC Business Intelligence Reporting System | | | | | | | |

Key Deliverables

| Project Name | Activity Name | Description | Planned Completion Date | Projected Completion Date | Actual Completion Date | Duration (in days) | Schedule Variance (in days) | Schedule Variance (%) |
|--------------|--|---------------------------|-------------------------|---------------------------|------------------------|--------------------|------------------------------|-----------------------|
| 283941 | 283941: Identify requirements and impacts of modifications related to implementation of Payable Analytics and planning functions in the BIRS/OBIEE environment | Planning and Requirements | 2011-12-30 | 2011-12-30 | 2012-03-23 | 120 | -84 | -70.00% |
| 283663 | 283663: 2010-11 Enhancements planned for contract year 1 include changes related to FSMA and the Oracle DB upgrade. | Planning and Requirements | 2011-12-30 | 2011-12-30 | 2011-10-31 | 212 | 60 | 28.30% |
| 284598 | 284598: 2011-2012 Enhance BIRS to include the capability for Payable Analytics and to make some planning functionality now in Hyperion available through BIRS | Planning and Requirements | 2012-03-15 | 2012-03-21 | 2012-03-20 | 182 | -5 | -2.75% |

Key Deliverables

| Project Name | Activity Name | Description | Planned Completion Date | Projected Completion Date | Actual Completion Date | Duration (in days) | Schedule Variance (in days) | Schedule Variance (%) |
|--------------|---|---------------------------|-------------------------|---------------------------|------------------------|--------------------|------------------------------|-----------------------|
| 283663 | 283663: 2011-12 Enhancements | Planning and Requirements | 2012-03-16 | 2015-10-15 | | 89 | -1,308 | -1,469.66% |
| 284598 | 284598: 2012-2013 BIRS enhancements to support FSMA and other changes | Planning and Development | 2012-09-30 | 2012-09-30 | | 153 | 0 | 0.00% |

Section C: Operational Data

Table II.C.1 Performance Metrics

| Metric Description | Unit of Measure | FEA Performance Measurement Category Mapping | Measurement Condition | Baseline | Target for PY | Actual for PY | Target for CY | Reporting Frequency |
|---|-----------------|---|-----------------------|------------|---------------|---------------|---------------|---------------------|
| ROI. Maintain or reduce Cost per dollar collected through UFFRS | dollars | Process and Activities - Financial | Under target | 0.001000 | 0.001000 | 0.001000 | 0.001000 | Semi-Annual |
| Maintain or reduce unscheduled down time as a result of application/UFFRS defects | percent | Technology - Reliability and Availability | Under target | 2.000000 | 2.000000 | 1.900000 | 1.000000 | Monthly |
| Maintain or reduce Cost per User | dollar | Technology - Technology Costs | Under target | 0.004000 | 0.004000 | 0.004000 | 0.004000 | Semi-Annual |
| Reduce execution time for key reports | time | Process and Activities - Cycle Time and Timeliness | Under target | 300.000000 | 10.000000 | 7.500000 | 8.000000 | Quarterly |
| Increase the number of BIRS users generating special reports | percent | Customer Results - Customer Benefit | Over target | 180.000000 | 5.000000 | 6.000000 | 5.000000 | Semi-Annual |
| Maintain or increase the number of regulatory actions that are supported by UFFMS | number | Mission and Business Results - Support Delivery of Services | Over target | 7.000000 | 7.000000 | 8.000000 | 7.000000 | Semi-Annual |